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July 6, 2012

BY ECF AND EMAIL

The Honorable Lois H. Goodman
United States Magistrate Judge
U.S. District Court for the
District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street Room 2020
Trenton, NJ 08608

Re: ***Orexo AB v. Mylan Pharmaceuticals, Inc., et al.***
3:11-cv-03788-FLW-LHG

Dear Judge Goodman:

Together with Kelley Drye & Warren, we represent the Mylan defendants in the above matter. We write in anticipation of the teleconference with Your Honor scheduled for this Monday July 9, concerning a dispute raised in the Joint Claim Construction and Prehearing Statement.

The dispute in essence is whether, consistent with the Local Patent Rules, a party (in this instance Mylan), as a result of or in the midst of the meet-and-confer process regarding disputed patent claim terms, may arrange, clarify, moderate or harmonize its position, and react to the negotiations and discussions that occur during that process on the meaning of disputed claim terms.

In contrast, Plaintiff's expressed view is that a party may adjust its proposed construction of a term *only* if it results in a complete agreement about the meaning of that term; otherwise a party cannot moderate or alter in any way its proposed construction of a term whose meaning remains in dispute, even if it results from the meet-and-confer process and conferences with the other party to the litigation.

Mylan respectfully submits that Plaintiff Orexo's view is directly contrary to the letter and spirit of the Local Patent Rules, and cannot be harmonized with those Rules or the Court's long-standing usage of the meet-and-confer process as a means of narrowing issues in dispute between parties, as demonstrated herein.

Honorable Lois H. Goodman, U.S.M.J.

July 6, 2012

Page 2 of 5

Background

On May 25, 2012, the parties exchanged their Preliminary Claim Constructions pursuant to Local Patent Rule 4.2(a) and their identification of evidence in support of their constructions pursuant to Local Patent Rule 4.2(b). In its submission, Mylan identified its two experts by name, disclosed that each expert “may testify regarding background information about how a skilled reader would understand the subject matter of the ‘910 patent, the use of the various claimed features in formulation, and [their] opinion that the constructions proposed herein by Mylan are the appropriate constructions.”

On June 8, 2012, the parties exchanged their identification of evidence in opposition to the other party’s constructions pursuant to Local Patent Rule 4.2(c). Mylan incorporated by reference the evidence it identified in its May 25, 2012 submission, and provided additional detail and evidence to rebut Orexo’s constructions.

On June 11, 2012, the parties conferred pursuant to Local Patent Rule 4.2(d). On June 13, 2012, Mylan sent to Orexo’s counsel proposed claim construction positions modifying its preliminary constructions, following up on the June 11 conference. A copy of Mylan’s June 13 email is attached. The parties discussed those constructions in a meet-and-confer the next day (June 14, 2012). In part as a result of Mylan’s modified constructions, the parties came to an agreement as to 11 of the 18 terms, leaving seven terms in dispute.

Orexo never objected during the meet-and-confer to Mylan’s proceeding on the June 13 constructions of the remaining seven terms, and Mylan relied on these claim constructions in the Joint Claim Construction and Prehearing Statement. Orexo raised its first objection to Mylan’s not returning to its preliminary claim constructions on June 20, 2012 – merely two days before the original due date of the Joint Claim Construction and Prehearing Statement.

The June 13 Proposed Constructions Narrowed The Issues

Consistent with the letter and spirit of the Local Patent Rules, Mylan’s June 13 modifications of its preliminary constructions consolidated several of the claim construction themes into the remaining disputed terms – as exemplified by the June 13 changes to the constructions of “essentially water-free” and “ordered mixture of microparticles of at least one pharmaceutically active agent adhered to the surfaces of carrier particles.” Those terms (emphasized below) follow one another in claim 1 of the ‘910 patent:

A pharmaceutical composition for the treatment of acute disorders by sublingual administration, ***comprising an essentially water-free, ordered mixture of microparticles of at least one pharmaceutically active agent adhered to the surfaces of carrier particles***, said particles being substantially larger than said microparticles and being water-soluble, and a bioadhesion and/or mucoadhesion promoting agent mainly adhered to the surfaces of the carrier particles.

Honorable Lois H. Goodman, U.S.M.J.

July 6, 2012

Page 3 of 5

The June 11 meet-and-confer made apparent that the disputes on these two terms focused on two interrelated themes: dry mixing and adherence. The discussion of the parties' constructions further revealed that the "dry mixing" theme was unnecessarily included in Mylan's proposed construction of both claim terms. In order to crystallize the issues, and, perhaps, come to an agreement on the non-water based portion of the ordered mixture term, Mylan refocused the claim construction theme of "dry mixture" to the "essentially water-free" construction, and focused the "ordered mixture" limitation on adherence.¹ As noted above, the June 13 alternative constructions were the topic of the June 14, 2012 meet-and-confer conference, and so Orexo was fully aware of Mylan's alternative proposed construction of the seven claim terms in dispute.

Mylan Acted In Full Accordance With The Local Rules

Mylan acted fully in accord with the Local Patent Rules when it modified its preliminary claim constructions as part of the meet-and-confer process. Local Patent Rule 4.2, itself, reveals that the initial submission of claim constructions is intended to be "preliminary" when it refers to the submissions as "*Preliminary Claim Constructions*." In the context of infringement and invalidity contentions, this District has noted that "while the Local Patent Rules strive to have a party establish their contentions early on, it is important to recognize that 'preliminary . . . contentions are still preliminary.'" *Oy Ajat*, 2012 WL 1067900 at *20 (D.N.J. Mar. 29, 2012) (discussing infringement contentions). The Local Patent Rules are "'not a straitjacket into which litigants are locked from the moment their contentions are served,' but instead, 'a modest degree of flexibility exists, at least near the outset.'" *TFH Publs., Inc. v. Doskocil Mfg. Co., Inc.*, 705 F. Supp. 2d 361, 366 (D.N.J. 2010) ((quoting *Comcast Cable Commcn's Corp., LLC v. Finisar Corp.*, 2007 WL 716131, at *2 (N.D. Cal. 2007)). These principles should apply at least as much to Local Patent Rule 4.2 "Preliminary Claim Constructions" as to the invalidity and infringement contentions contemplated by Local Patent Rule 3 *et seq.*

Indeed, the meet-and-confer requirements of Local Patent Rules 4.1(b) and 4.2(d) further buttress the explicit "preliminary" nature of the claim constructions and the expectation that the parties will revise and modify their preliminary positions. Orexo seems to view the purpose of the meet-and-confer process in the Local Patent Rules as only allowing the parties to come to full agreement on issues, not to narrow those issues. There is, however, no principled reason why the Local Patent Rules would allow a modification only in the instance of an agreed construction and not in the instance where modified disputed constructions assist in achieving agreement on other terms. It would undermine the Local Patent Rules' meet-and-confer requirement to require the parties to revert to their preliminary positions in the absence of complete agreement on all claim terms, because a meet-and-confer is not supposed to be merely a debate where each party tries to convince the other party that it is wrong, but rather a discussion where conflicting views are exchanged frankly and positions sometimes modified in

¹ Mylan proposed one further modification after June 13, which was for "essentially water free." However, in view of Orexo's objections and our continuing effort to narrow the issues, Mylan is willing to proceed with its June 13 constructions *in toto*.

Honorable Lois H. Goodman, U.S.M.J.

July 6, 2012

Page 4 of 5

an effort to narrow the issues the Court must decide. Certainly when each party was given fair notice of any revision of the constructions – which the June 13 email shows happened here – modification of preliminary constructions made during the meet-and-confer process that narrow the terms in dispute is not proscribed by the Local Rules.

**Orexo Similarly Misinterprets the Local Rules Concerning Evidentiary Support
for Claim Constructions**

Mylan's citation of evidence in the Joint Claim Construction and Prehearing Statement complies with the Local Patent Rules. Orexo's arguments with respect to supposed "new matter" are without merit and do not reflect the facts. For the most part, Orexo argues that Mylan violated the Local Patent Rules when Mylan quoted the same evidence it quoted in its Local Patent Rule 4.2 disclosures, but provided bold/italics emphasis or additional attorney explanation in the Joint Claim Construction and Prehearing Statement to the same evidence it quoted in its Local Patent Rule 4.2 disclosures. Orexo also apparently seems to argue that Mylan's disclosure of expert testimony was insufficient. Orexo is wrong on both counts.

With respect to the additional attorney argument and the simple addition of bold/italic emphasis to quotations. Orexo relies on Local Patent Rule 4.3(f) and this Court's Feb 7, 2012 Pre-Trial Scheduling Order ¶ 19(f) in support of its argument, but neither requires parties to put forth a "cut-and-paste" of their Local Patent Rule 4.2 disclosures. Rather they both state: "Any *evidence* that is not identified under L. Pat. R. 4.2(a) through 4.2(c) inclusive shall not be included in the Joint Claim Construction and Pre-hearing Statement." (emphasis added). Thus, the prohibition on "new matter," is limited to the addition of new evidence. Additional attorney explanation of the evidence and the addition of bold-italics emphasis is not "evidence." As such, the rules, and this Court's order do not prohibit Mylan from using different words in its explanations or different emphasis of quoted excerpts in the Joint Claim Construction and Prehearing Statement to help describe its positions for Orexo and the Court.

Orexo also objects that, for some pieces of evidence, Mylan copied evidence disclosed with respect to one term in the prior disclosures to support the construction of a second term in the Joint Claim Construction and Prehearing Statement. Orexo does not cite to any rule that parties cannot do this – particularly when a party modified the constructions as part of the meet-and-confer process envisioned by the Local Patent Rules. Indeed, Local Patent Rule 4.2 does not even require parties to disclose their evidence in the form of claim charts – as they do for infringement and invalidity contentions. *See* L. Pat. R. 3 et seq. (requiring "charts").

Finally, Orexo seems to take issue with the level of disclosure of Mylan's expert testimony. Mylan timely identified its two experts by name, and it disclosed that each expert would speak to the appropriate claim construction for all of the terms. Mylan provided additional explanation regarding the expert disclosure information in its June 8, 2012 disclosure and in its portion of the Joint Claim Construction and Prehearing Statement.

Mylan met its disclosure objections and thus Orexo's objections are not well-founded. For instance, Orexo argues that Mylan failed to disclose expert testimony concerning disclaimer of cross-linked polyvinylpyrrolidone in connection with the term "bioadhesion and/or

Honorable Lois H. Goodman, U.S.M.J.

July 6, 2012

Page 5 of 5

mucoadhesion promoting agent” – a required element of all of the claims. This argument is very hard to understand. Mylan disclosed that it would be presenting expert testimony from either Drs. Augsburger or Elder with respect to the term “bioadhesion and/or mucoadhesion promoting agent” and the correct construction of that term. (Mylan’s Preliminary Claim Construction at 34; Mylan’s Response at 25, 34.) Mylan also specifically disclosed that it was going to present expert testimony showing how the applicants of the ‘910 patent “disclaimed cross-linked polyvinylpyrrolidone in the prosecution history.” (Mylan’s Response at 21.)

Conclusion

We thank the Court for its consideration of this letter and we look forward to next Monday’s teleconference with the Court.

Respectfully submitted,



Arnold B. Calmann

ABC/rdt

cc: All Counsel of Record (by ECF & e-mail)

To: Arnie Calmann
 Subject: RE: Orexo v. Mylan, 3:11-cv-03788

From: Koutsoubas, Constantine [mailto:CKoutsoubas@KelleyDrye.com]
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 To: 'etaylor@milbank.com'; 'fzullo@milbank.com'; 'Sreepada, Suni'
 Cc: Santiago, David A.; Jacob, Beth; Katz, Clifford; Hochstetler, Douglass; McVary, Barrett; Arnie Calmann; Jeffrey Soos; Katherine A. Escanlar; Kim, Sung W.; 'estole@cov.com'; 'jflaherty@mccarter.com'; 'jshort@mccarter.com'; 'manania@mccarter.com'; 'crodrigue@mccarter.com'; 'eslavin@mccarter.com'; 'wmcnamara@milbank.com'
 Subject: Orexo v. Mylan, 3:11-cv-03788

Counsel,

Following up on our conversation on Monday, please consider the attached document. We note that we are still reviewing the alternative claim construction positions in the attached document, but we just wanted to provide you with our latest thoughts in advance of our call tomorrow.

First, as you will note, the attached document breaks up some of the claim elements in the way that Orexo did in its preliminary claim construction document. Mylan still has concerns about the way that Orexo has parsed some claim elements into their individual components for construction, but Mylan has followed Orexo's format in the attached document in the hope that it would focus the discussion tomorrow and assist in further narrowing the claim construction issues for the Court.

In addition, please let us know if there are any terms that you think are missing from this list, or terms that should be viewed as disputed or as undisputed (or vice versa).

Finally, we note that in Orexo's responsive pleading to Mylan's preliminary identification of evidence in support of its claim constructions, Orexo argues that Mylan "is improperly trying to hide the ball in violation of the letter and spirit of Local Rule 4.2" because Mylan cited and quoted from too much evidence.

Local Patent Rule 4.2 merely requires the parties to disclose their "preliminary claim constructions" (Local Patent Rule 4.2(a)) and the intrinsic and extrinsic evidence that support those constructions (Local Patent Rule 4.2(b)). Mylan has done that. As such, Mylan's disclosures comply with Local Patent Rule 4.2.

Nevertheless, to the extent Orexo is unable to determine how and why any particular piece of evidence quoted in any of the charts supports the particular claim construction, we would be pleased to discuss this during tomorrow's teleconference as part of an overall effort to narrow the claim construction issues.

Sincerely

Dino

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7/6/2012

Disputed Terms

<u>Term</u>	<u>Proposed Construction</u>
Ordered mixture	A mixture of carrier particles and adherent particles of an active pharmaceutical agent
Essentially water-free	No water is intentionally added during the manufacturing process
Microparticles of at least one pharmaceutically active agent	Particles of the active agent have a particle size no greater than about 24 microns
Adhered to the surfaces	Binding to the surfaces
Substantially larger	Substantially greater than 24 microns
Bioadhesion and/or mucoadhesion promoting agent	<p>A substance that is effective in making the active agent adhere to the oral mucosa.</p> <p>For the '910 patent, neither microcrystalline cellulose nor cross-linked polyvinylpyrrolidone is such an agent.</p>
Treatment	Control
Effective amount of at least one pharmaceutically active agent in the form of microparticles adhered to the surfaces of carrier particles	The amount sufficient for treatment of an acute disorder is in the form of microparticles adhered to the surfaces of carrier particles.

Undisputed Terms

<u>Term</u>	<u>Proposed Construction</u>
Pharmaceutical composition	A formulation suitable for medical use
Acute disorders	Medical conditions where a rapid and transient effect is desirable, such as insomnia and breakthrough pain (e.g. in cancer patients)
Sublingual administration	Placing under the tongue so that the active agent is available for absorption through the oral mucosa
Carrier particles	Particles comprising a material such as mannitol that is pharmaceutically acceptable and soluble in water
“Mainly”	Principally
Weight based mean diameter	A mean diameter determined on a weight basis. (Orexo’s position)
Brittle material	No need to construe at this time. (Orexo’s position)
Wherein the carrier particles contain from 0.1 to 25 percent of the bio/mucoadhesion promoting agent	No need to construe at this time. (Orexo’s position)
At least one pharmaceutical disintegrating agent promoting the dispersion of the microparticles of the active agent or agents over the sublingual mucosa.	No need to construe at this time. (Orexo’s position)
Water soluble	No need to construe at this time. (Orexo’s position)
Individually effective	No need to construe at this time. (Orexo’s position)